REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Status of Claims

Claims 1, 3, 4, and 6-10 are pending in the application. Claims 1, 3, 4, and 6-10 have been rejected.

CLAIM REJECTIONS

35 U.S.C. § 103 Rejections

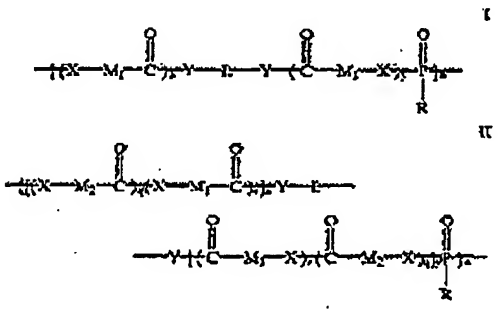
In the Office Action, the Examiner rejected claims 1, 3, 4, and 6-10 under 35 U.S.C. § 103(a), as being unpatentable over Mao et al. The Examiner alleged that Mao disclosed: (a) biodegradable medical implant devices that incorporate 1-65% active agent; (b) that any antipsychotic drugs (e.g. clozapine, haloperidol, and risperidone) can be used; and (c) use of lactic acid/glycolic acid copolymers. The Examiner alleged that "The difference... between Mao and the instant claims is [only] the amount of the haloperidol" (page 3, first full paragraph of the October 19, 2006 Office Action). Therefore, Examiner alleged that it would have been obvious to modify the implant of Mao to arrive at the implants claimed in the subject claims.

Applicants respectfully traverse the rejection. Contrary to the Examiner's allegations, the compositions recited in the subject claims are not obvious over the Mao reference. Moreover, the Examiner has not established a prima facia case of obviousness over Mao. The Examiner has not shown, based on Mao, any of: (a) suggestion or motivation to modify the implants disclosed therein to arrive at the implants recited in the subject claims; (b) a reasonable expectation of success for making or using the implants recited in the subject

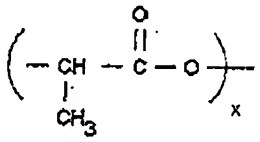
claims; or (c) that Mao teaches or even suggests all the claim limitations of the subject claims. Each of these points is clearly described hereinbelow.

Specifically, the compositions recited in the subject claims have nothing in common with those disclosed in Mao. The subject claims are directed to a surgically implantable drug delivery system consisting essentially of a biodegradable polymer or copolymer selected from the group consisting of polylactide and lactide-co-glycolide copolymer and 20 to 40% haloperidol fabricated into an individual, surgically implantable implant via solvent casting and compression molding at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of a patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more and is removable from the patient in the event the patient exhibits unwanted side effects following implantation.

By contrast, the polymers of Mao have 1 of the following formulas:

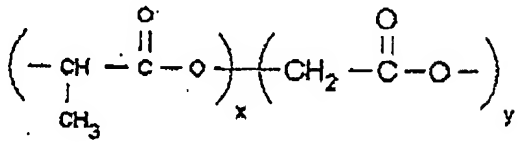


Applicants respectfully point out to the Examiner that, in addition to the presence of numerous other substituents that do not appear in the polylactide and lactide-co-glycolide copolymers of the subject invention, the polymers disclosed in Mao contain a phosphate linkage, as clearly depicted in formulas I and II above. By contrast, polylactide and lactide-co-glycolide copolymers of the subject invention do not contain a phosphate linkage. Polylactide polymers have the formula:



Lactide-co-glycolide copolymers have the formula:

$$[OCH(CH_3)CO]_x[OCH_2CO]_y$$



No phosphate is present in either of the above formulas.

As described hereinbelow, the phosphate group contained in the polymers of Mao affects the basic and novel characteristics of the polymers of Mao. Thus, the polymers of Mao do not "consist essentially of a biodegradable polymer or copolymer selected from the group consisting of polylactide and lactide-co-glycolide copolymer," as recited in the subject claims. Further, the polymers of Mao are quite different in their characteristic from polymer of the present invention, as described hereinbelow.

Further, Applicants respectfully point out to the Examiner that the alleged disclosure of polylactide and lactide-co-glycolide copolymers in columns 12-13 of Mao is limited, as clearly stated in column 12, line 50 of Mao, to the use of polylactide and lactide-co-glycolide copolymers as reagents ("prepolymers") for use in step (b) of the synthesis reaction described in column 11, lines 44-55 of Mao. The purpose of step (b) is to create "interconnecting phosphorylated units" (column 13, lines 36-37). The cited passage does not disclose or contemplate the use of the unmodified prepolymers. Accordingly, the disclosure of Mao teaches nothing about polymers that do not contain a phosphate moiety; e.g. polymers of the present invention.

Further, Applicants respectfully assert that the polymers of the subject invention are not obvious in view of Mao. Further, the biological functionality of the phosphate group present in the polymers of Mao is important in defining the disclosure of Mao. Mao admits that the phosphate group is critical for the biological functionality, as it affects the properties of the polymers disclosed therein:

> "The polymers of formulas I and II are usually characterized by a release rate of the biologically active substance *in vivo* that is controlled at least in part as a

function of hydrolysis of the phosphoester bond of the polymer during biodegradation" (column 14, lines 25-36).

Further, Mao indicates that the presence of the phosphate group confers ability to incorporate an active compound into the polymers disclosed therein:

"Additionally, the biologically active substance to be released may be conjugated to the phosphorus sidechain R' to form a pendant drug delivery system" (column 14, lines 36-38).

Thus, if Mao states that the phosphate group is central and critical to Mao's disclosure, one cannot remove the phosphate and/or replace it with another moiety, as the Examiner is asserting. Doing so would completely alter the polymers and resulting implants from the entire disclosure of the invention.

In summary, Mao taught that the phosphate moieties present in the implants disclosed therein are important both in incorporation of a drug into the polymer and in determining the drug release rate. Clearly, Mao contains no suggestion to remove the phosphate moieties. Thus, implants of the present invention are not obvious in view of Mao.

Further, Mao neither discloses nor suggests the combination of haloperidol with any polymers of the subject invention. As described hereinabove, the polymers of Mao, which contain a phosphate group, are unrelated to the polymers of the present invention, which consist essentially of polylactide and lactide-co-glycolide copolymers. Applicants respectfully assert that there is no way a person of ordinary skill in the art would see in Mao a suggestion to combine haloperidol with a polymer of the subject invention, without a disclosure or suggestion in Mao of the polymers themselves.

Further, Mao neither discloses nor suggests the range of 20-40% haloperidol, as recited in the subject claims. Rather, Mao merely provides a broad, generic range of 1-65%, with no disclosure or suggestion of the 20-40% range recited in the subject claims.

Accordingly, many structural and chemical differences are present between the implants disclosed in the Mao and those recited in the subject claims. Applicants respectfully assert that the Examiner's rationale for rejecting the subject claims has depended on the erroneous understanding that the implants disclosed in the Mao differ from those of the

subject invention only in the drug percentage, as alleged on page 3, first full paragraph of the October 19, 2006 Office Action.

Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner alleged that Mao disclosed preparation of biodegradable implants by melt processing or by compression molding.

Applicants respectfully assert that Examiner's allegation is irrelevant to the subject claims. Claim 4 recites a method that comprises both solvent casting and compression molding. "Melt processing" is a completely distinct process from solvent casting. Thus, the alleged disclosure cited by the Examiner is irrelevant to the subject claims. Further, Mao does not disclose a process that comprises both solvent casting and compression molding.

Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner alleged that Mao disclosed that the antipsychotic drugs can have an effect over schizophrenia and can be used with expectation of a synergistic effect. Therefore, Examiner alleged that it would have been obvious to use the implant of Mao to treat schizophrenia.

Applicants respectfully disagree. Contrary to the Examiner's allegations, the implants allegedly disclosed in Mao are structurally and chemically unrelated to the implants recited in the subject claims. Accordingly, the above allegation is irrelevant to the claimed subject matter.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the

prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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